

**REMARKS**

Claims 1-76 are pending in the present application.

By this Amendment, claims 1, 42 and 48 are amended. Claims 12 and 14 are being re-presented in amended form for reconsideration per the telephone interview conducted on August 18, 2003. Dependent claims 13, 15-19, 22, 23, 25, 27, 29, 31, 33, 36, 37, 40, 41, 45, 47, 57, 58, 64, 65, 71 and 72 are being re-presented for reconsideration without amendment. No new matter has been added by the amendments or by the re-presentation of claims. It is respectfully submitted that claims 1-76 are in condition for allowance in view of the amendments and remarks presented herein.

Applicant gratefully acknowledges the courtesies extended to Applicant's representatives by Examiner Sharareh during the August 18, 2003 telephone interview. The points discussed during that interview are incorporated herein. In particular, claim 1 is generally amended in accordance with our discussion with Examiner Sharareh.

**SUMMARY OF ACTION**

Claims 1-76 are pending in the above-captioned application. The Office Action rejects Claims 1-11, 20, 21, 24, 26, 28, 30, 34, 35, 38, 39, 42-44, 48-56, 59-63, 66-70, 73-76 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 14, 18, 20, 22, 24, 26, 28, 29, 32, 33, 36-38, and 42-46 of U.S. Patent No. 6,281,236 in view of Venkitaraman et al. (U.S. Patent No. 5,871,762) or Yamanaka et al. (U.S. Patent No. 5,176,916). Claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al. (JP 58-140013) in view of Grollier et al. (U.S. Patent No. 4,767,618) and Venkitaraman et al. (U.S. Patent No.

5,871,762). Claims 1-11, 20, 21, 24, 26, 28, 30, 32, 34, 35, 38, 39, 42-44, 48, 56, 59, 63, 66, 70 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al. (JP 58-140013) in view of Grollier et al. (U.S. Patent No. 4,767,618) and Venkitaraman et al. (U.S. Patent No. 5,871,762) as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and further in view of Grollier (U.S. Patent No. 4,880,621), Chodosh (U.S. Patent No. 5,661,170), Briggs et al. (U.S. Patent No. 5,871,754) and Yamanaka et al. (U.S. Patent No. 5,176,916) as applied to claims 6-11, 21, 32, 38, 39, 56 and 59. Applicant gratefully acknowledges the indication by Examiner Sharareh that claims 49-55, 60-62, 67-69 and 74-76 contain allowable subject matter.

**Double Patenting**

Claims 1-11, 20, 21, 24, 26, 28, 30, 34, 35, 38, 39, 42-44, 48-56, 59-63, 66-70, 73-76 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 14, 18, 20, 22, 24, 26, 28, 29, 32, 33, 36-38, and 42-46 of U.S. Patent No. 6,281,236 in view of Venkitaraman et al. (U.S. Patent No. 5,871,762) or Yamanaka et al. (U.S. Patent No. 5,176,916).

The Terminal Disclaimer filed herewith obviates these rejections. Accordingly, withdrawal of these rejections is respectfully requested.

**Claim Rejections - 35 U.S.C. § 103(a)**

Claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Minoru Kuroda et al. (JP 58-140013) (hereinafter “Kuroda”) in view of Grollier et al. (U.S. Patent No. 4,767,618) and Venkitaraman et al. (U.S. Patent No. 5,871,762).

The Office Action states, among other things, “the pH of the compositions disclosed in JP ‘013 ranges between 4-7, which overlaps with the instant pH ranges. In fact, JP ‘013 encourages the use of lower ranges of such pH for improving the stability of allantoin.”

Kuroda discloses several allantoin-containing compositions containing no more than 0.4% allantoin having pH values of approximately 4-7. Kuroda, however, specifically indicates that if the topical composition as disclosed and claimed is “adjusted below pH 4, it is not desirable for the skin.... (Pg.6).” Kuroda also states that “those samples of the topical application agent of this invention prepared with their pH in the range of 4-7 showed no changes in appearance and usage after storage at room temperature for 8 months or 40°C for 3 months.” In the next sentence, however, Kuroda further states (as evidenced by Table 2) that “the results with respect to allantoin content showed that those samples prepared at pH 4 and pH 5 were excellent, and the allantoin content was found to be reduced at pH 6-7” (Pg. 6). Kuroda, therefore, does not teach or suggest an allantoin-containing composition comprising “over 0.4% allantoin” as recited in independent claims 1 and 48 and in re-presented independent claims 12 and 14. Furthermore, Kuroda does not teach or suggest adjusting the pH of the allantoin-containing compositions comprising over 0.4% of allantoin “to a value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C” as recited in independent claims 1 and 48 and in re-presented independent claims 12 and 14. Kuroda thus fails to teach or suggest the features of independent claims 1 and 48, of re-presented independent claims 12 and 14 and of the corresponding dependent claims.

The Office Action asserts that Grollier discloses a number of components that may be included in oil-in-water emulsions, including beeswax, herbal components, surfactants solvents and perfumes.

Grollier discloses a number of compositions, some of which contain allantoin. None of these allantoin-containing compositions, however, disclose pH values. Furthermore, none of the compositions disclosed in Grollier disclose stability of the compositions at a particular temperature and/or over a particular time period. Accordingly, Grollier does not teach or suggest an allantoin-containing compositions comprising over 0.4% of allantoin wherein the pH is adjusted “to a value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C” as recited in independent claims 1 and 48 and in re-presented independent claims 12 and 14. Grollier thus fails to teach or suggest the features of independent claims 1 and 48, of re-presented independent claims 12 and 14 and of the corresponding dependent claims.

The Office Action states that Venkitaraman “comprises a therapeutic oil-in-water emulsion that can contain an anioinic surfactant system and a therapeutic drug (abstract; col 4, lines 14-25 and 43-47). The emulsions used with Venkitaraman’s applicator typically has a pH ranging from 2-10 and should be stable for at least 2 days at the temperature of about 120 deg F (about 48 deg C).” The Office action also states, in paragraph 14, that Venkitaraman’s “applicators lack an oil-in-water emulsion containing allantoin.”

Venkitaraman discloses applicators impregnated with certain oil-in water emulsions. Venkitaraman also states that “the oil-in-water emulsion compositions of the present invention are stable for at least 2 days at 120°F, preferably for at least 5 days at 120°F, more preferably for at least about 2 weeks at 120°F, and most preferably for at least 6 weeks at 120°F.” Venkitaraman does not teach any applicators containing allantoin. Thus, Venkitaraman does not teach or suggests an applicator impregnated with an oil-in-water emulsion comprising over 0.4% of allantoin and a pH “value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C” as recited in independent claims 1 and 48 and in re-presented independent claims

12 and 14. Venkitaraman thus fails to teach or suggest the features of independent claims 1 and 48, of re-presented independent claims 12 and 14 and of the corresponding dependent claims.

The combined teachings of Kuroda, Grollier and Venkitaraman fail to provide the features of independent claims 1 and 48, re-presented independent claims 12 and 14 and of the corresponding dependent claims as described above. In addition, Kuroda, Grollier and Venkitaraman do not provide the requisite motivation to combine or modify their teachings to arrive at the invention recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. In particular, none of the references discloses allantoin-containing compositions or applicators impregnated with allantoin-containing compositions comprising over 0.4% of allantoin with a pH “value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C” as recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. Thus, it is respectfully submitted that Kuroda, Grollier and Venkitaraman fail to teach or suggest the invention recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. Therefore, withdrawal of the rejection of claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 under 35 U.S.C. § 103(a) is respectfully requested.

Claims 1-11, 20, 21, 24, 26, 28, 30, 32, 34, 35, 38, 39, 42-44, 48, 56, 59, 63, 66, 70 and 73 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kuroda et al. (JP 58-140013) in view of Grollier et al. (U.S. Patent No. 4,767,618) (“Grollier I”) and Venkitaraman et al. (U.S. Patent No. 5,871,762) as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and further in view of Grollier (U.S. Patent No. 4,880,621) (“Grollier II”), Chodosh (U.S. Patent No. 5,661,170), Briggs et al. (U.S. Patent No. 5,871,754) and Yamanaka et al. (U.S.

Patent No. 5,176,916) as applied to claims 6-11, 21, 32, 38, 39, 56 and 59. Claims 6-11, 21, 32, 38, 39 and 56 depend from independent claim 1. Claim 59 depends from independent claim 48.

Applicant reiterates the comments set forth above regarding Kuroda et al. (JP 58-140013), in view of Grollier et al. (U.S. Patent No. 4,767,618) and Venkitaraman et al. (U.S. patent No. 5,871,762) as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73. Specifically, none of the references discloses allantoin-containing compositions, or applicators impregnated with allantoin-containing compositions, comprising over 0.4% of allantoin with a pH “value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C” as recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. Additionally, the Office Action states that the combined teachings of Grollier I and Venkitaraman “fail to explicitly teach the use of butylated hydroxytoluene as an antioxidant, citric acid and hydrochloric acid as pH modifiers, EDTA as the chelator, and bandages as an applicator component.”

The Office Action states that Grollier (U.S. Patent No. 4,880,621) “is essentially the same teachings as Grollier I, except that it also sets forth the antioxidants such as butyl hydroxytoluene and butyl hydroxyanisole are art recognized equivalents....”

Grollier II discloses a number of compositions, some of which contain allantoin. None of these allantoin-containing compositions, however, disclose pH values. Furthermore, none of the compositions disclosed in Grollier II disclose allantoin stability for the compositions at particular temperatures and/or over particular time periods. Grollier II, therefore, does not supply the deficiencies of the combination of Kuroda, Grollier I and Venkitaraman as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and thus fails to teach or suggest the features of dependent claims 6-11, 21, 32, 38, 39, 56 and 59.

The Office Action asserts that Chodosh “is merely used to show that citric acid is conventionally employed as a pH modifier in allantoin containing emulsions and that it along with ascorbic acid and malic acid, and strong acids such as hydrochloric acid are conventional acidifying agents.” While Chodosh discloses a number of formulations, some containing allantoin, none of the compositions disclose allantoin stability at particular temperatures and/or over particular time periods. Chodosh, therefore, does not supply the deficiencies of the combination of Kuroda, Grollier I and Venkitaraman as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and thus fails to teach or suggest the features of dependent claims 6-11, 21, 32, 38, 39, 56 and 59.

The Office Action states that Briggs “also teaches allantoin oil-in-water emulsions, but it is used to show that chelating agents such as EDTA are among conventional adjuvants used in oil-in-water emulsion systems. Briggs discloses allantoin compositions, among others, with concentrations no higher than 0.1%. Furthermore, none of the compositions disclose allantoin stability at particular temperatures and/or over particular time periods. Briggs, therefore, does not supply the deficiencies of the combination of Kuroda, Grollier I and Venkitaraman as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and thus fails to teach or suggest the features of dependent claims 6-11, 21, 32, 38, 39, 56 and 59.

The Office Action asserts that Yamanaka teaches “polymeric applicators in the form of bandages that are readily used for administration of topical formulation such as oil-in-water emulsions.” The Office Action also states that Yamanaka’s, as well as Venkitaraman’s, “applicators lack an oil-in-water emulsion containing allantoin.” Yamanaka, therefore, does not supply the deficiencies of the combination of Kuroda, Grollier I and Venkitaraman as applied to

claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and thus fails to teach or suggest the features of dependent claims 6-11, 21, 32, 38, 39, 56 and 59.

The combined teachings of Kuroda, Grollier I and Venkitaraman as applied to claims 1-5, 20, 24, 26, 28, 30, 34, 35, 42-44, 48, 63, 66, 71 and 73 and further in view of Grollier II, Chodosh, Briggs and Yamanaka as applied to claims 6-11, 21, 32, 38, 39, 56 and 59 fail to provide the features of independent claims 1 and 48, re-presented independent claims 12 and 14 and of the corresponding dependent claims. In addition, Kuroda, Grollier I, Venkitaraman, Grollier II, Chodosh, Briggs and Yamanaka do not provide the requisite motivation to combine or modify their teachings to arrive at the invention recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. In particular, none of the references discloses allantoin-containing compositions or applicators impregnated with allantoin-containing compositions comprising over 0.4% of allantoin with a pH "value from about 3.0 to about 6.0, the allantoin being stable for at least 90 days at 40°C" as recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. Thus, it is respectfully submitted that Kuroda, Grollier I, Venkitaraman, Grollier II, Chodosh, Briggs and Yamanaka fail to teach or suggest the invention recited in independent claims 1 and 48, in re-presented independent claims 12 and 14 and in the corresponding dependent claims. Therefore, withdrawal of the rejection of claims 1-11, 20, 21, 24, 26, 28, 30, 32, 34, 35, 38, 39, 42-44, 48, 56, 59, 63, 66, 70 and 73 under 35 U.S.C. § 103(a) is respectfully requested.

**Re-entry of Previously Withdrawn Claims**

During the personal interview, Applicants' representatives requested re-entry of previously restricted claims 12-19, 22, 23, 25, 27, 29, 31, 33, 36, 37, 40, 41, 45-47, 57, 58, 64,



65, 71 and 72. Applicant's representatives noted that these claims are similar to claims in commonly owned U.S. Patent No. 6,281,236, that claims certain compositions related to the applicators claimed in the present application. Examiner Sharareh indicated that he would consider allowing claims 12-19, 22, 23, 25, 27, 29, 31, 33, 36, 37, 40, 41, 45-47, 57, 58, 64, 65, 71 and 72 to be re-entered. Thus, claims 12-19, 22, 23, 25, 27, 29, 31, 33, 36, 37, 40, 41, 45-47, 57, 58, 64, 65, 71 and 72 are reintroduced by the Amendment.

**CONCLUSION**

In view of the foregoing, Applicant respectfully requests the reconsideration and timely allowance of the pending claims. Should the Examiner feel that there are any issues outstanding after consideration of this response, the Examiner is invited to contact Applicant's undersigned representative to expedite prosecution.

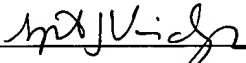
If there are any other fees due in connection with the filing of this response, please charge the fees to our Deposit Account No. 50-1349. If a fee is required for an extension of time under 37 C.F.R. § 1.136 not accounted for above, such an extension is requested and the fee should also be charged to our Deposit Account.

Respectfully submitted,

**HOGAN & HARTSON LLP**

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